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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/530,164

04/04/2005

Susanne Binder

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7590

01/23/2009

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EXAMINER

KIM, TAEYOON

ART UNIT

PAPER NUMBER

1651

MAIL DATE

DELIVERY MODE

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

<p align="center">Advisory Action Before the Filing of an Appeal Brief</p>	<p>Application No. 10/530,164</p>	<p>Applicant(s) BINDER ET AL.</p>	
	<p>Examiner TAEYOON KIM</p>	<p>Art Unit 1651</p>	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 29 December 2008 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

- a) ☐ The period for reply expires _____ months from the mailing date of the final rejection.
- b) ☒ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☒ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
- (a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);
- (b) ☒ They raise the issue of new matter (see NOTE below);
- (c) ☒ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
- (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: See Continuation Sheet. (See 37 CFR 1.116 and 41.33(a)).

4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☒ Applicant's reply has overcome the following rejection(s): See Continuation Sheet.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☒ will not be entered, or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
- The status of the claim(s) is (or will be) as follows:
- Claim(s) allowed: _____.
- Claim(s) objected to: _____.
- Claim(s) rejected: 42,43,45-49,53-59 and 61.
- Claim(s) withdrawn from consideration: 60.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.
12. ☐ Note the attached Information *Disclosure Statement*(s). (PTO/SB/08) Paper No(s). _____
13. ☐ Other: _____.

/Leon B Lankford/
Primary Examiner, Art Unit 1651

Continuation of 3. NOTE: The newly introduced limitation of "non-immortalized" in claim 42 raises a new matter issue to the application. In amended cases, subject matter not disclosed in the original application is sometimes added and a claim directed thereto. Such a claim is rejected on the ground that it recites elements without support in the original disclosure under 35 U.S.C. 112, first paragraph, *Waldemar Link, GmbH & Co. v. Osteonics Corp.* 32 F.3d 556, 559, 31 USPQ2d 1855, 1857 (Fed. Cir. 1994); *In re Rasmussen*, 650 F.2d 1212, 211 USPQ 323 (CCPA 1981). See MPEP § 2163.06 - § 2163.07(b) for a discussion of the relationship of new matter to 35 U.S.C. 112, first paragraph. New matter includes not only the addition of wholly unsupported subject matter, but may also include adding specific percentages or compounds after a broader original disclosure, or even the omission of a step from a method. See MPEP § 608.04 to § 608.04(c). See *In re Wertheim*, 541 F.2d 257, 191 USPQ 90 (CCPA 1976) and MPEP § 2163.05 for guidance in determining whether the addition of specific percentages or compounds after a broader original disclosure constitutes new matter.

Continuation of 5. Applicant's reply has overcome the following rejection(s): If the amendment enters, the claim rejection under 35 U.S.C. §102 and 35 U.S.C. §103 based on Dutt et al. would be withdrawn.

Continuation of 11. does NOT place the application in condition for allowance because: As indicated above, the current amendment, if entered, would overcome the claim rejection under 35 U.S.C. §102. In the response to the claim rejection under 35 U.S.C. §103 based on Young et al. and supporting references, applicant argued that the present application provides the unexpected result that 16,000 to about 20,000 non-immortalized RPE or RPE equivalent cells per 4 mm² of amniotic membrane can be seeded and grown directly on the amniotic membrane, and do not need to be transferred onto the membrane as an epithelial monolayer sheet. First of all, there is no clear evidence to prove the alleged unexpected results. It is true that Young et al. disclose the use intact epithelium as one embodiment. It is believed that this rationale is based on the findings that RPE in suspension do not form an intact monolayer and have not been shown to be beneficial in the treatment of human disease (p.3, lines 27-29). Therefore, "intact" epithelium/monolayer is required for the better treatment. Since Young et al. clearly teach that amniotic membrane is an alternative to Bruch's membrane, and in order to have RPE cells on amniotic membrane similar to the "intact" epithelium/monolayer, one could use intact epithelium or cells in suspension to fully cover the entire surface of the given amniotic membrane. Therefore, a person of ordinary skill in the art would use a sufficient number of RPE cells in order to form a complete monolayer (entirely covering the surface of amniotic membrane) on the amniotic membrane to mimic the "intact" epithelium. Although Young et al. do not disclose that the number of RPE cells to entirely cover 4 mm² of amniotic membrane, the number required to entirely cover the area would be easily obtainable by a person of ordinary skill in the art. Furthermore, it is intrinsic property of epithelial cells including RPEs to form tight junctions when cells are under confluent condition, and because of such formation, apical and basolateral polarity is formed. As applicant pointed out, it is true that the polarity frequently lost when epithelial cells are cultured as a monolayer. However, this does not prevent one skilled in the art from using RPE cells as a sheet or being seeded and cultured on amniotic membrane as a graft.

With regard to the claim rejection based on Liu in view of supporting references, applicant argued that there is no motivation to replace collagen substrate of Liu with amniotic membrane since Liu or other references does not teach or suggest culturing non-immortalized RPE on an amniotic membrane. This is not persuasive since Liu teaches the use of RPE cells which is harvested from normal tissue, and thus it is non-immortalized RPE cells. The use of amniotic membrane in place of collagen is supported by Dutt et al. as well as Young et al.

Based on the above discussion, the current application is considered not in condition for allowance.

Taeyoon Kim
AU-1651